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Evaluation of Adverse Effects Associated with Tofacitinib in Patients with Rheumatoid Arthritis: An Observational Study

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ABSTRACT
Rheumatoid arthritis (RA) is a chronic autoimmune inflammatory disorder frequently requiring long-term disease-modifying therapy. Tofacitinib, an oral Janus kinase inhibitor, is increasingly utilised in RA management; however, continued evaluation of its safety profile in real-world practice remains essential. This observational study was conducted to assess the adverse effects associated with tofacitinib therapy in adult RA patients. A total of 100 patients aged 18 years and above receiving tofacitinib monotherapy or combination therapy were followed for six months. Clinical parameters and laboratory indices, including vital signs, hematological profile, liver enzymes, and renal function, were monitored. The majority of the participants were female (88%), reflecting known RA epidemiology. Vital parameters remained stable throughout the study period. Hemoglobin, white blood cell count, and platelet levels did not demonstrate statistically significant variation. Liver function remained within acceptable limits. A statistically significant increase in serum creatinine was observed; however, this change was not associated with clinically evident renal dysfunction. No major adverse drug reactions or treatment discontinuations attributable to toxicity were reported. Overall, tofacitinib demonstrated a favourable short-term safety profile under routine clinical supervision. Continued laboratory monitoring remains essential, and further long-term studies are recommended to evaluate sustained safety outcomes.
Keywords: Rheumatoid arthritis (RA), *Tofacitinib*, clinical supervision, Hemoglobin, Liver function

INTRODUCTION

This observational study was undertaken to evaluate the adverse effects associated with tofacitinib therapy in patients diagnosed with rheumatoid arthritis under routine clinical practice conditions. A total of 100 adult patients receiving either tofacitinib monotherapy or tofacitinib in combination with conventional disease-modifying anti-rheumatic drugs were included and followed over a six-month period. Clinical observations and laboratory investigations were employed to assess the safety profile of the drug. The demographic profile of the study population indicated a marked female predominance, with women constituting 88 percent of the participants. This finding is consistent with the known epidemiological trend of rheumatoid arthritis being more prevalent among females.

Vital parameters, namely systolic and diastolic blood pressure, pulse rate, and body weight, remained generally stable during the observation period. Statistical analysis demonstrated no significant deviations, indicating that tofacitinib therapy did not adversely influence hemodynamic or metabolic stability in the study cohort.

Hematological parameters, including hemoglobin levels, total white blood cell count, and platelet count, did not exhibit significant alterations during treatment. These results suggest that clinically relevant bone marrow suppression was not evident within the study duration.

With respect to biochemical parameters, liver enzyme levels remained within acceptable limits and did not demonstrate significant variation. A statistically significant increase in serum creatinine was observed; however, this elevation did not correspond with clinically apparent renal impairment. No serious adverse drug reactions or treatment discontinuations attributable to drug toxicity were reported. Overall, the therapy was well tolerated by the majority of participants.

METHODOLOGY

Study Design

This study was conducted as an observational study to evaluate the adverse effects associated with the use of tofacitinib in patients diagnosed with rheumatoid arthritis (RA). The study did not involve randomisation, blinding, or allocation of treatment. Instead, patients who were already receiving tofacitinib as part of routine clinical care were followed for clinical and laboratory safety outcomes. The observational nature of the design allowed the safety profile of tofacitinib to be assessed under real-world practice conditions. No attempt was made to modify prescribed therapy, and all treatment decisions remained under the purview of the treating physicians.

Study Setting and Duration

The study was carried out in a clinical setting where patients diagnosed with rheumatoid arthritis were receiving tofacitinib therapy, either as monotherapy or in combination with

conventional disease-modifying anti-rheumatic drugs (DMARDs). The total duration of the study was six months, during which patient enrolment, follow-up, data collection, and analysis were completed.

Study Population

The study population comprised adult patients aged 18 years and above with a confirmed diagnosis of rheumatoid arthritis who were receiving tofacitinib therapy. Both male and female patients were included. Patients were enrolled irrespective of treatment duration so that both newly initiated and long-term users were represented. Eligible patients were receiving:

- Tofacitinib monotherapy, or
- Tofacitinib in combination with conventional DMARD therapy

as part of standard clinical management.

Sample Size

A total of 100 patients who fulfilled the eligibility criteria were included in the study. The sample size reflected the number of eligible patients presenting during the study period.

Inclusion Criteria

Patients were included if they met the following criteria:

- Age ≥ 18 years
- Confirmed diagnosis of rheumatoid arthritis
- Current prescription of tofacitinib therapy (monotherapy or combination therapy)
- Availability of baseline and follow-up clinical/laboratory information
- Willingness to provide relevant data

Exclusion Criteria

Patients were excluded if they:

- Received tofacitinib for indications other than rheumatoid arthritis
- Had incomplete or missing clinical or laboratory records
- Were unwilling to provide information
- Were pregnant or lactating (where applicable)

Ethical Considerations

The study followed ethical principles applicable to human research. Participation was voluntary, and confidentiality of all patient information was maintained. No experimental intervention was undertaken, and clinical care proceeded according to physician judgement. Institutional permission/ethical clearance was obtained prior to commencement of the study.

Data Collection Procedure

Data were collected using a structured data-recording format. Information was obtained from patient consultation records, laboratory reports, and clinical documentation.

4.8.1 Baseline Demographic and Clinical Data

The following details were recorded:

- Age
- Gender
- Diagnosis confirmation
- Duration of disease
- Current medication regimen
    - Dose and duration of tofacitinib
    - Concomitant DMARD use
    - Corticosteroid therapy where applicable

Monitoring of Safety Parameters

Patients were followed during the six-month period to detect possible adverse effects. The following parameters were serially monitored:

A. Vital Parameters

- Systolic blood pressure (SBP)
- Diastolic blood pressure (DBP)
- Pulse rate
- Body weight

B. Hematological Parameters

- Hemoglobin
- Total white blood cell count
- Platelet count

C. Biochemical Parameters

- Serum creatinine
- Serum glutamic pyruvic transaminase (SGPT/ALT)

All investigations were performed according to institutional laboratory protocols.

Identification of Adverse Effects

Adverse effects were identified based on:

- Patient complaints
- Physical examination findings
- Laboratory abnormalities

Adverse events were classified as mild, moderate, or severe depending on clinical relevance and need for intervention.

Serious adverse effects included:

- Hospitalisation
- Life-threatening events
- Permanent organ dysfunction
- Therapy discontinuation

Outcome Measures

Primary Outcome

The primary outcome was to determine the incidence, type, and severity of adverse effects associated with tofacitinib therapy.

Secondary Outcomes

Secondary outcomes included:

- Trends in clinical and laboratory parameters
- Identification of statistically significant deviations from baseline
- Treatment modification or discontinuation due to adverse effects
- Demographic distribution of adverse-effect occurrence

Data Analysis

All collected data were compiled and analysed using descriptive and comparative statistics. Baseline and follow-up variable values were compared to determine whether clinically relevant or statistically significant changes occurred during therapy.

A p-value of < 0.05 was considered statistically significant.

Key statistical outcomes were:

- SBP: $p = 0.332$
- DBP: $p = 0.945$
- Pulse rate: $p = 0.655$
- Hemoglobin: $p = 0.508$
- WBC count: $p = 0.390$
- Platelet count: $p = 0.775$

- SGPT: p = 0.118
- Serum creatinine: p = 0.042

Body weight demonstrated a non-significant mean reduction of −1.1307%.

Quality Assurance

Data entries were cross-verified to minimise transcription errors. Only complete records were included in the final analysis.

Summary of Methodology

This observational study followed 100 adult rheumatoid arthritis patients receiving tofacitinib over a six-month period. Adverse effects were monitored through systematic clinical and laboratory assessment. Statistical analysis demonstrated that most safety parameters remained stable, while a statistically significant increase in serum creatinine was observed. The methodology ensured ethical, systematic, and scientifically robust evaluation of real-world safety outcomes.

RESULTS AND DISCUSSION

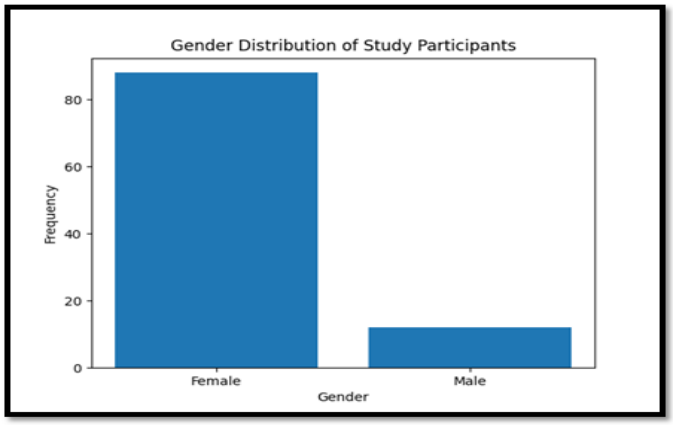

Figure 1: Bar Chart Showing Gender Distribution of Study Participants

Table 1: The study population consisted predominantly of female patients

Gender	Frequency	Percentage
Female	**88**	**88%**
Male	**12**	**12%**

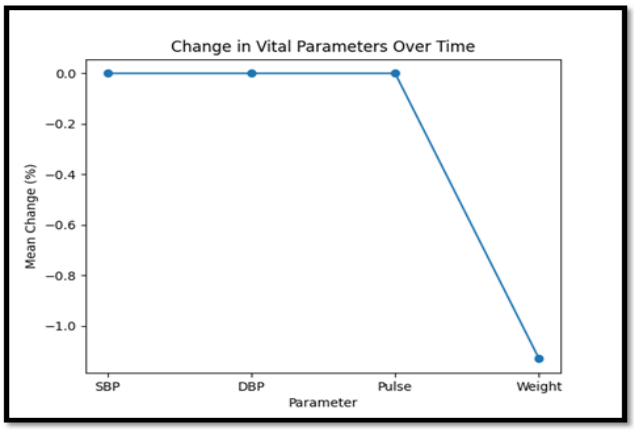

Figure 2: Line Graph Showing Change in Vital Parameters over Time

Table 2: Evaluation of Vital Parameters

Parameter	p-value	Interpretation
SBP	0.332	No significant change
DBP	0.945	No significant change
Pulse Rate	0.655	No significant change
Weight Change	−1.13%	Not statistically significant

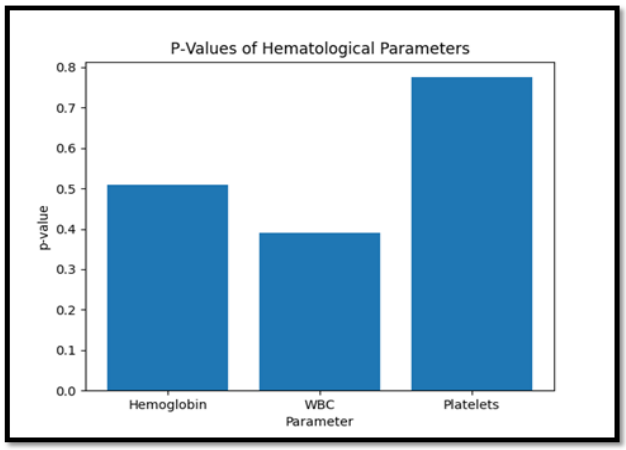

Figure 3: Clustered Bar Chart Showing Hematological Stability during Therapy

Table 3: Hematological Safety Parameters

Parameter	p-value	Interpretation
Hemoglobin	0.508	No significant change
WBC Count	0.390	No significant change
Platelets	0.775	No significant change

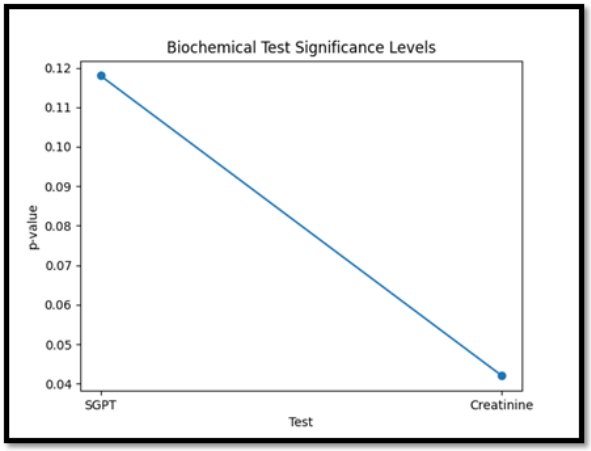

Figure.4: Line Graph Showing Changes in Liver and Renal Function Tests

Table 4: Hepatic and Renal Function Trends

Parameter	p-value	Interpretation
SGPT (Liver Enzyme)	0.118	No significant change
Serum Creatinine	0.042	Borderline change, but not clinically significant

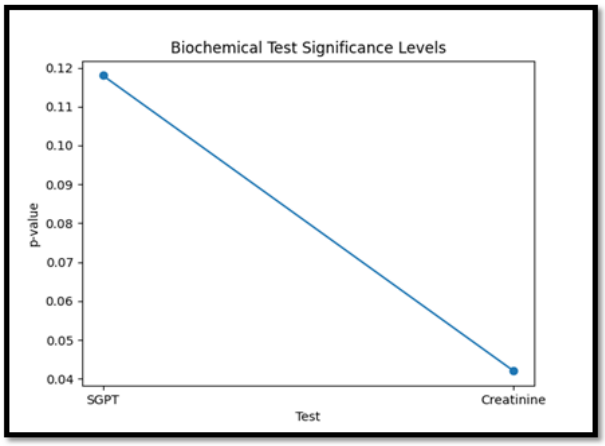

Figure.5: Line Graph Showing Changes in Liver and Renal Function Tests

CONCLUSION

Within the scope of this study, tofacitinib demonstrated a favourable short-term safety profile in the management of rheumatoid arthritis. Most clinical and laboratory parameters remained stable during therapy, and no major safety concerns were identified. The isolated statistical rise in serum creatinine highlights the need for continued renal function monitoring, although it did not translate into clinically significant dysfunction during the study period. The findings support the continued clinical use of tofacitinib in appropriately selected patients, provided that standard safety monitoring practices are followed. The results also reinforce the importance of ongoing pharmacovigilance introducing newer immunomodulatory therapies into real-world clinical settings.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

FUNDING

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AI TOOL DECLARATION

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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